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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,720	08/25/2003	Christine Markert-Hahn	810102.401	3616

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EXAMINER	
TUNG, JOYCE	

ART UNIT	PAPER NUMBER
1637	

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08/12/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/647,720	MARKERT-HAHN ET AL.	
	Examiner	Art Unit	
	Joyce Tung	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The response filed 5/04/09 to the Office action has been entered. Claims 1 and 3-11 are pending.

1. Claims 1 and 3-5 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Herman et al. (5,786146, issued July 28, 1998) in view of Gerdes et al. (6,291,166, issued Sep. 18, 2001).

Herman et al. disclose a methylation specific PCR (See the Abstract). The method involves the step of conversion cytosine to uracil. Bisulfite modification includes incubating the nucleic acid in the presence of sulfite ions, binding the deaminated nucleic acid to a solid phase. Modified DNA was purified. Modification was completed by NaOH treatment, followed by ethanol precipitation (See column11, lines 16-28).

Herman et al. do not disclose that a nucleic acid is bound to a solid phase and then the nucleic acid is deaminated.

Gerdes et al. disclose a method of using solid phases to irreversibly capture RNA or DNA and teaches true, direct solid phase manipulation and analyses including enzyme recognition, hybridization and amplification (see column 3, lines 39-49, column 4, and lines 45-48).

One of ordinary skill in the art would have been motivated to apply a solid phase bound DNA as taught by Gerdes et al. in the method of Herman et al. because as taught by Gerdes et al. a solid phase bound nucleic acid can be directly and conveniently manipulated (see column 4, lines 45-46) and can be applied in various ways for example treating/manipulating/analyzing/amplifying nucleic acids (see column 4, lines 43-48). It would

have been prima facie obvious to use solid phase bound nucleic acid as recited in the instant claims.

The response argues that Herman et al. fail to teach performing a deamination reaction on solid phase, while Herman et al. teach a deamination reaction in solution. The response further argues that bisulfite ions only interact with cytosines that do not participate in base-pairing and the Declaration of Dr. Markert-Hahn filed 4/15/08 indicates that a single-stranded DNA was believed to interact with a solid phase as if it were participating in base-paring. However, Gerdes et al. teach that immobilized nucleic acid can be directly manipulated in which the immobilized nucleic acid can be double stranded or single stranded (see the abstract). Therefore, based upon the teachings of Herman et al. in view of Gerdes et al., it would have been prima facie obvious to use solid phase-bound nucleic acid for deamination.

The response argues that Gerdes et al. require that the nucleic acid is neither altered nor exhausted during analysis and in no way relates to chemically modifying nucleic acid. However, Gerdes et al. disclose binding of DNA in a binding buffer containing NaOH or guanidine buffer (see column 8, lines 9-10). The binding reaction as taught by Gerdes et al. is interpreted as a chemical reaction or chemical modification.

The response further argues that Gerdes et al. do not disclose a bisulfie reaction on solid-phase bound nucleic acid. However, the teachings of Gerdes et al. are used as a secondary reference for a 103 rejection and not for a 102 rejection.

The response also argues that the method of Gerdes et al. requires that the solid-phase bound nucleic acid is un-denatured to allow analyses of the bound nucleic acid by interaction with other molecules, while Herman et al. requires denatured nucleic acids, making the two

references incompatable. However, as mentioned above, Gerdes et al. disclose that immobilized nucleic acid can be double stranded or single stranded (see the abstract) and the denaturation of nucleic acid in the method of Herman et al. makes it single stranded. Therefore, one of ordinary skill would have been motivated to combine the teachings of Gerdes et al. and Herman et al. to carry out the method as claimed.

Based analysis above, the rejection is maintained.

2. Claims 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herman et al. (5,786146, issued July 28, 1998) in view of Gerdes et al. (6,291,166, issued Sep. 18, 2001) as applied to claims 1 and 3-5 above, and further in view of Weindel et al. (WO 01/37291, issued May 21, 2001).

The teachings of Herman et al. and Gerdes et al. are set forth in section 1 above.

Herman et al. do not disclose that the solid phase comprises magnetic glass particle, the magnetic particle has diameter between 0.5 and 5um, and the magnetic glass particle is manufactured by the sol-gel method.

Weindel et al. disclose the magnetic glass particle, which can be used in nucleic acid purification (See the abstract). The magnetic glass particle is a solid dispersion of small magnetic core in glass (See pg. 4, lines 9-11). The diameter of the particle is between 5 and 500nm (See pg. 4, lines 21-23 and pg. 5, lines 13-23). The magnetic glass particle is used in nucleic acid purification from a sample containing cells. The advantage of this is its potential simplicity and high sensitivity (See pg. 17, lines 1-7). Weindel et al. also disclose the method of making the magnetic glass particle by the sol-gel method and spray-drying as recited in instant claim 11 (See

pg. 9, lines 13-37, pg. 21 and fig. 1). The magnetic glass particle is also used in nucleic acid amplification and hybridization assay (See pg.1).

One of ordinary skill in the art would have been motivated to apply the magnetic glass particle of Weindel et al. in the method of Herman et al. as a solid support for converting cytosine bases to uracil bases because of the advantage of using the magnetic glass particle (See pg. 17, lines 1-17). It would have been prima facie obvious to apply the magnetic glass particle for the conversion of cytosine bases to uracil bases in a nucleic acid.

Since the response does not have a specific argument for the rejection. The rejection is maintained with the same reasons as set forth above.

Summary

3. No claims are allowed.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kenneth R Horlick/
Primary Examiner, Art Unit 1637

/Joyce Tung/
Examiner, Art Unit 1637
August 5, 2009